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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,117	11/13/2001	Elliott Farber	14358-315	3442
24633	7590	06/15/2005	EXAMINER	
HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,117

Applicant(s)

FARBER, ELLIOTT

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,77-92 and 106-138 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,77-92 and 106-138 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/29/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on March 29, 2005 has been entered. Claims 1-5, 77-92, 106-138 are now pending. Page 6 of the Amendment recites that claims 106-140 are added, but only claims 106-138 were found in the Amendment. Clarification is requested.

Any rejection or objection that is not addressed in this Office Action is considered obviated in view of the claim amendments and/or the submitted Terminal Disclaimer. Examiner's responses to applicant's arguments are addressed with each pending grounds of rejection below.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Minoru Kuroda et al JP 58-140013 (JP '013) (see entire translation).

3. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant argues that Kuroda fails to suggest an allantoin-containing composition with pH values of about 3-6 being stable for at least 90 days at 40 deg C. (see Arguments at page 13).

4. In response Examiner states that Applicant's interpretation of JP '013 appears to be in error. JP '013 clearly discloses topical oil-in-water emulsions comprising allantoin, an acidic wax such as white vasoline, paraffin or squalane with the pH of the ranges of ranges between 4-7 for at least 90 days (3 months) at 40deg C. (see example 1 at page 4 and the last three lines of page 5 of the translation). JP '013 also specifically recites

Art Unit: 1617

the use anionic surfactants namely sodium alkyl sulfates such as sodium lauryl sulfate.
(see claims 1, pages 2-3, examples 1).

Finally, it has been well established that when a prior art teaches a range within, overlapping or touching the claimed range, the prior art is indeed an anticipatory reference, if the prior art range discloses the claimed range with sufficient specificity. (see MPEP 2131.03). Here, the compositions of JP '013 have a pH of 4-7, which overlaps with the instantly claimed pH ranges of 3-6. The JP '013 teaches, with specificity, compositions having pHs of 4 ± 0.2 , 5 ± 0.2 , 6 ± 0.2 , 7 ± 0.2 (see the last line of the page 3 translation). Accordingly, JP '013's compositions also anticipate the instantly claimed ranges.

Claim Rejections - 35 USC § 103

5. Claims 106-109, 127-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation).
6. JP '013 discloses topical oil-in-water emulsions comprising allantoin (see claim 1). The emulsions of JP '013 further contain a higher fatty acid such as stearic acid (a C_{18} organic acid) and cetyl alcohol. JP '013 also states that anionic surfactants namely sodium alkyl sulfates such as sodium lauryl sulfate may be employed in such emulsions if desired (see claims 1, the entire pages 2-3, 5-6, especially examples 1). The pH of the compositions disclosed in JP '013 ranges between 4-7, which overlaps with the instant pH ranges. In fact, JP '013 encourages the use of lower ranges of such pH for improving the stability of allantoin. JP '013 formulations are stable for a period of 3

Art Unit: 1617

months at 40 deg, C. (see page 5). JP '013 only fails to employ higher concentrations of allantoin in his formulations.

However, absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the concentrations of allantoin by routine experimentations. One of ordinary skill in the art would have had a reasonable expectation of success in achieving such results, because he would have only had to modify one parameter of JP '013 formulation, namely the concentrations of allantoin, by routine experimentations to observe an enhanced stability

7. Claims 1-5, 77-86, 106-122, 127-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier 4,933,177 (Grollier I) and Grollier et al US Patent 4,767,618 (Grollier II).

8. The teachings in JP '013 are described above. JP '013 only lacks in reciting various components such as specific anionic or nonionic surfactants, triethanolamine stearate, herbal ingredients, tetrasodium EDTA, and paraban derivatives.

9. Grollier I and II are complementary and provide general knowledge in the art about the use of various types of topical and cosmetic ingredients and their combination with allantoin.

10. Grollier I discloses oil-in-water emulsion compositions that contains allantoin, propylene glycol, mineral oils, fatty body wax such as carnaba wax or bees wax, thickening agents such as guar gum, alginates, methyl cellulose and starch that meet the requirement of instant carbohydrate polymers (see col 6, lines 6-60; col 6, line 6, 56,

Art Unit: 1617

example 18, 22-, 32, 34-3623). Grollier finally claims a composition that contains various plant ingredients such as witch hazel, in combination with a fatty body, such as beeswax, a thickening agent such as a carbohydrate polymer, an emulsifier such as sodium lauryl sulfate in oil-in water emulsion. (see col 16, lines 50-64). Accordingly, Grollier I meets the limitations of the instant claims.

11. Grollier II discloses oil-in-water emulsion compositions that can contain beeswax as a component, which assists oil retention (see col 6, lines 53-56; col 5, line 49).

Grollier II also teaches the use of herbal components in such oil-in-water emulsions.

Grollier I also teaches the use of anionic surfactants such as sodium lauryl sulfate as emulsifying agents (see col 6, lines 5-13), lanolin oil, and cod liver oil as the oil phase (see col 5, line 27-30; col 6, line 40-41), propylene glycol or cetyl alcohol as solvents (col 5, lines 5-12; col 16, lines 30-35), perfume of choice, anti-inflammatory and antiseptic such as allantoin (col 16, line 34-35), a pH modifier, antioxidants such as butyl hydroxyanisole, and preservative agents such as methyl parahydroxybenzoate (methylparaban, see RN 99-76-3), or propyl parahydroxy benzoate (propylparaben, see RN 94-13-3) (see col 6, lines 56-60; col 14, lines 20-23). Thus, Grollier II anticipates the limitations of the instant claims.

12. It has been held that the selection of known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding cosmetic components of interest including oil retention

Art Unit: 1617

agents such as beeswax, emollients such as cetyl alcohol, herbal components of choice such as chamomile or St. John's wort, and other topical adjuncts such as preservatives as taught and pH modifiers including citric acid, and a chelating agent such as EDTA, as taught by Grollier II to provide a topical formulation with optimal intended basic cosmetic material.

13. The court has reasoned a reasonable expectation of success in the art by stating that reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll co.*, 325 U.S. at 335, 65 USPQ at 301. Since all elements of the instant claims are taught in the cited references to be employed in oil-in-water emulsion systems combining them for their own intended use would have been *prima facie* obvious.

14. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant argues that JP '013 does not teach the stability and pH ranges of the instant base claims 1 and 77. (Remarks at page 15). In response, as elaborated above, Examiner maintains his position that JP '013 clearly teaches such limitations. (see para 3-4 *supra*).

15. Applicant then argues that there is no motivation in the art to modify or combine the cited references. (see Arguments at page 15). In response, Examiner states that the courts have clearly embraced the case of *prima facie* obviousness when the case merely employs known material based on its suitability for its intended uses. *Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly, it

Art Unit: 1617

would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding cosmetic components of interest including oil retention agents such as beeswax, and suitable herbal components of choice such as chamomile or St. John's Wort, as taught by Grollier II, because the ordinary skill in the art would have had a reasonable expectation of success to improve the quality of the cosmetic compositions of JP '013 by adding suitable ingredients for their own the intended benefits.

16. Claims 87-92, 123-126, 135-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier et al US Patent 4,767,618 (Grollier II), as applied to claims 1-5, 77-86, 106-122, 127-134 and further in view of Grollier US Patent 4,880,621 (Grollier III), Briggs et al US Patent 5,871,754.

17. The teaching of JP '013 and Grollier II, are discussed above. Their combined teachings fail to explicitly teach the instantly recited concentrations and the use of butylated hydroxytoluene as an antioxidant.

18. Grollier III is essentially the same teachings as Grollier II, except that it also sets forth that antioxidants such as butyl hydroxytoluene and butyl hydroxyanisole are art recognized equivalents (see col 8, lines 42-44; col 9, lines 43-45).

19. Briggs is merely used to show that allantoin oil-in-water emulsions that chelating agents such as EDTA are among conventional adjuvants used in oil-in-water emulsion systems (see col 10, lines 45-col 11, lines 10).

20. The teachings of JP '013, Grollier I, II, III, and Briggs are considered to be in the same field of endeavor, because they all provide for topical administration of oil-in-water emulsion systems.

21. As reasoned above, It has been held that the selection of known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll co. V. Interchemcial Corp.*, 65 USPQ 297. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding cosmetic components of interest including oil retention agents such as beeswax, emollients such as cetyl alcohol, herbal components of choice such as chamomile or St. John's wort, and other topical adjuncts such as preservatives as taught and pH modifiers including citric acid, antioxidants such as butylhydroxytoluene, and a chelating agent such as EDTA, as taught by Grollier II and III, and further exemplified by Briggs.

22. The ordinary skill in the art would have had a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll co.*, 325 U.S. at 335, 65 USPQ at 301. Thus, since all elements of the instant claims are taught in the cited references to be employed in oil-in-water emulsion systems combining them for their own intended use would have been *prima facie* obvious.

Art Unit: 1617

23. Finally, the question of whether a particular parameter can be optimized or not is addressed in *In re Antoine*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Accordingly, absence of showing unexpected results, discovery of an optimum value of a variable in a known invention is obvious when parameter optimized was recognized to be a result-effective variable. Therefore, Examiner views optimization of the amounts of the instant ingredients is well within the level of ordinary skill in the art and a matter of routine experimentation.

Recommendations

24. Amending claims 87-92, 123-126 with a limitation that addresses the stability requirement of allantoin for 90 days at 40 deg C would be considered favorably, because the art does not seem to suggest the stability of allantoin at the claimed higher concentrations in combination with the recited ingredients for a duration of 90 days at 40 deg C.

Conclusion

25. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action because the scope of the claims have been modified. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

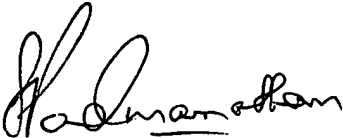
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER